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A5R RAM

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US 4447915 A US 4276659 A US 4245359 A

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(54) Cement restrictor for a medullary canal

(57) An expandable cement restrictor comprises an inner member (2) nested within an outer member (1). The members (1, 2) are each formed from a plurality of longitudinal segments (3, 4) which in a non-expanded state are positioned very close to if not touching one another. The restrictor further comprises an expansion body (5) which is positionable within the inner member (2). The restrictor is placed in a medullary canal, and once it has been located in an appropriate position, the expansion body is pulled into the nested inner and outer members (1, 2) to cause the expandable body to dig into the bone of the canal and hold the restrictor in position. A lug on the inner member engages a recess in the outer member to prevent relative rotation of the members. When expanded the longitudinal segments (3, 4) of the inner and outer members overlap circumferentially.

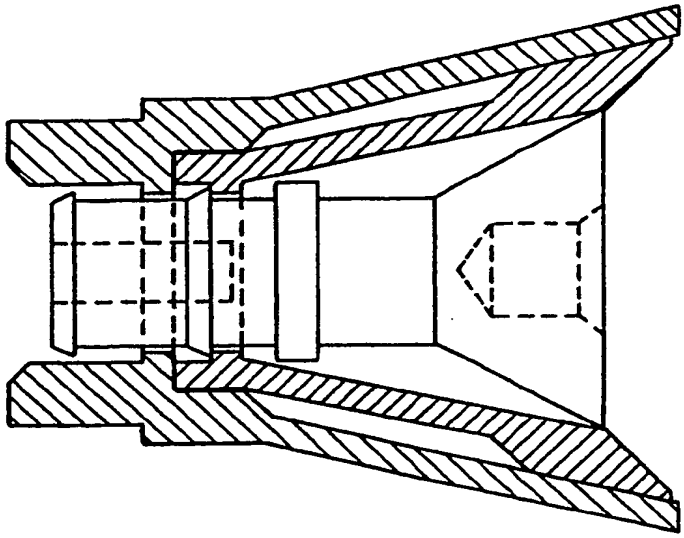

FIG. 2b

At least one drawing originally filed was informal and the print reproduced here is taken from a later filed formal copy.

The claims were filed later than the filing date within the period prescribed by Rule 25(1) of the Patents Rules 1990.

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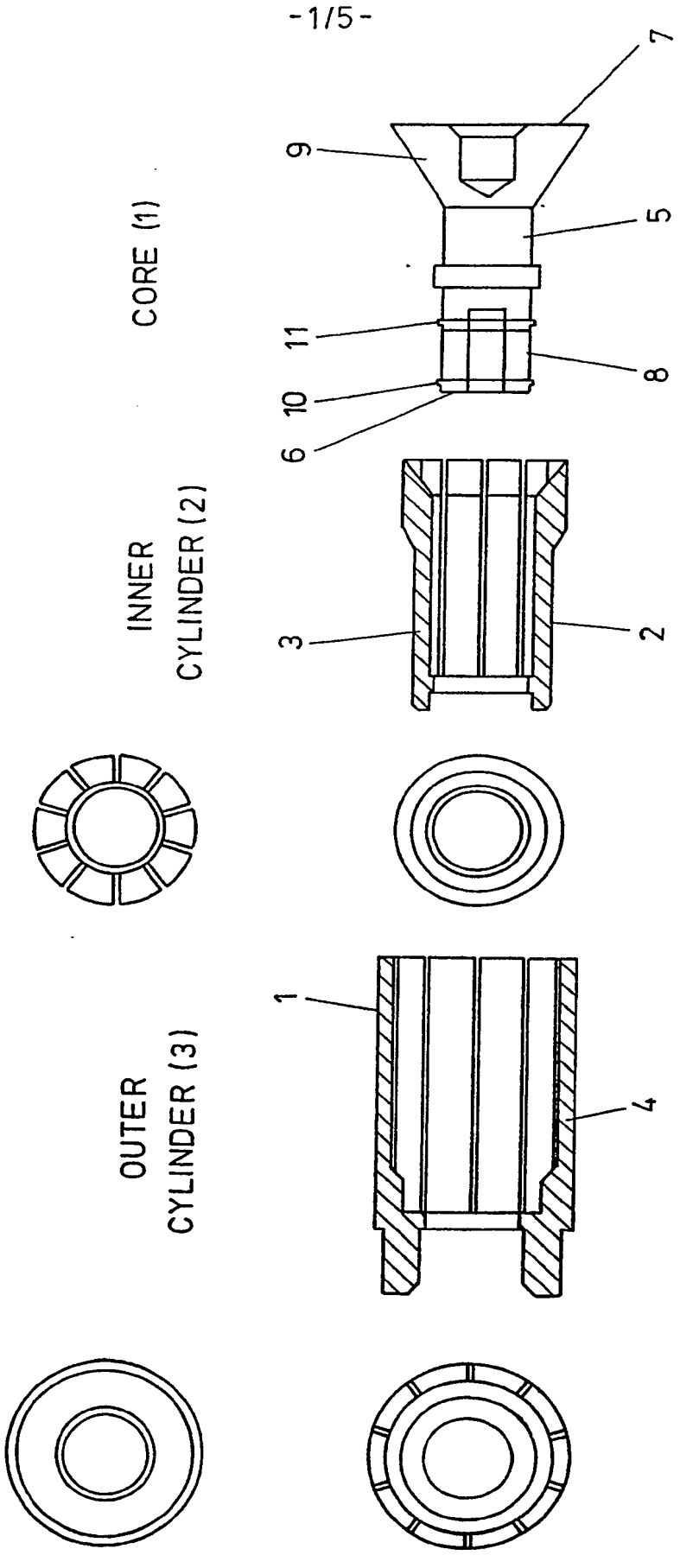

FIG. 1

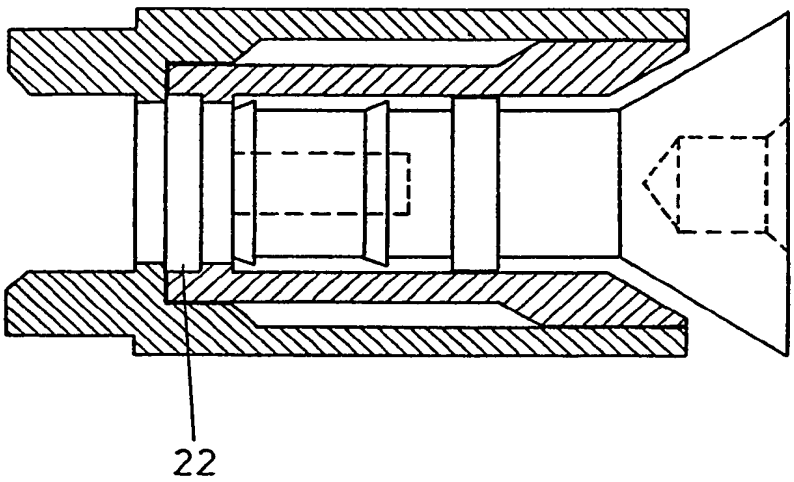

FIG. 2a

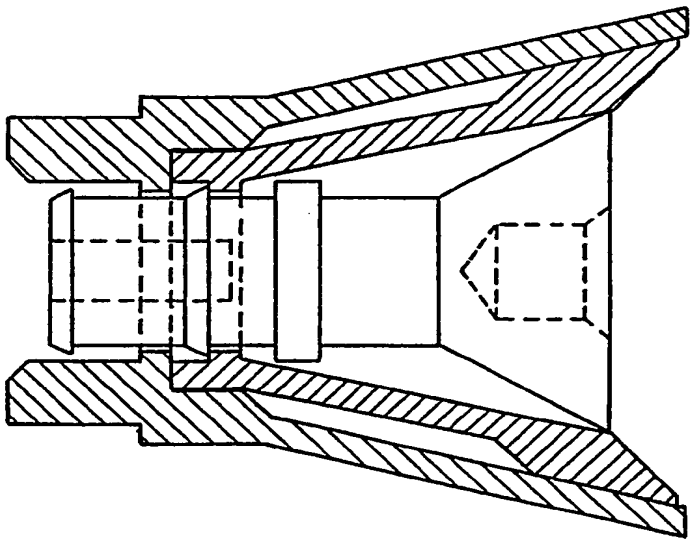

FIG. 2b

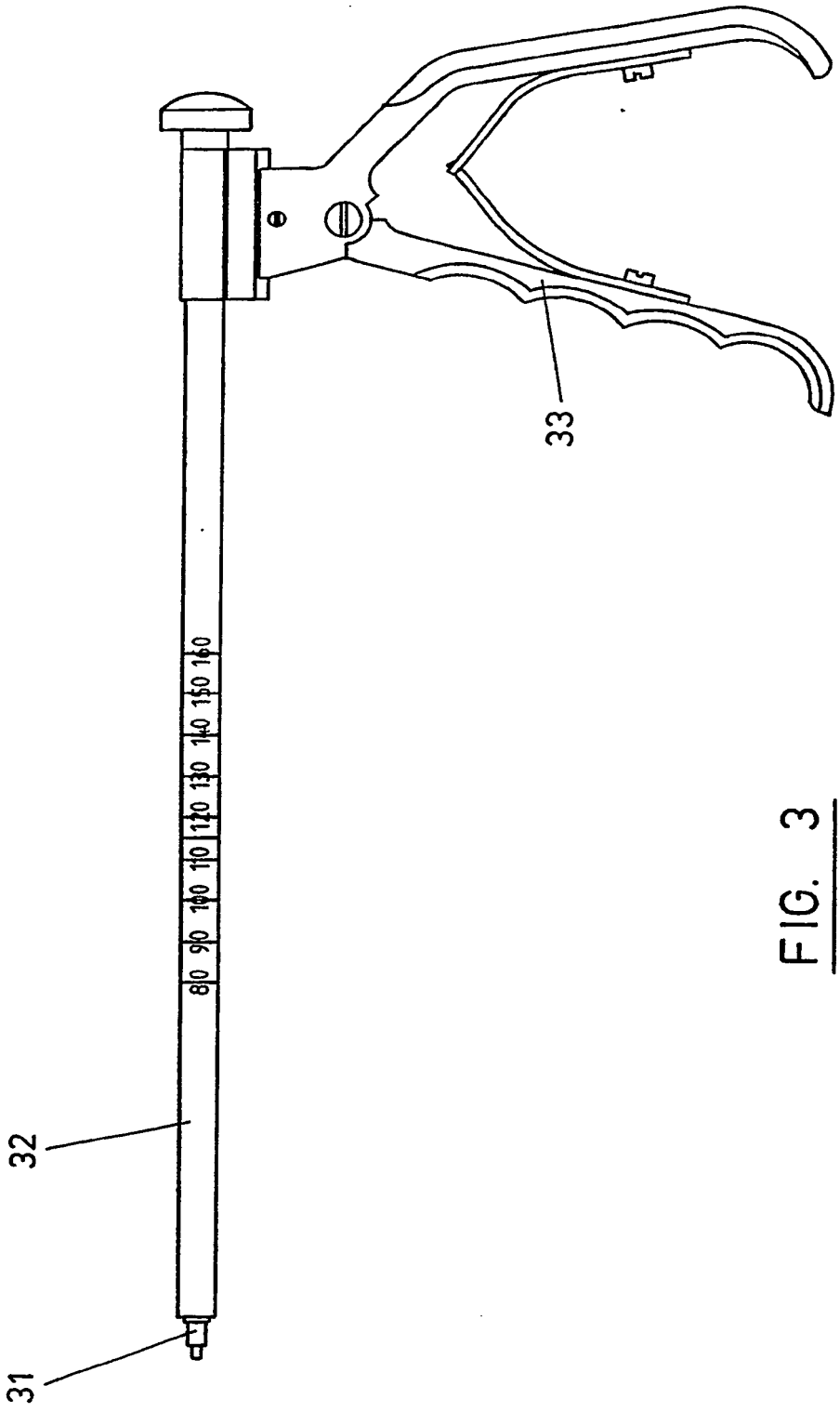

FIG. 3

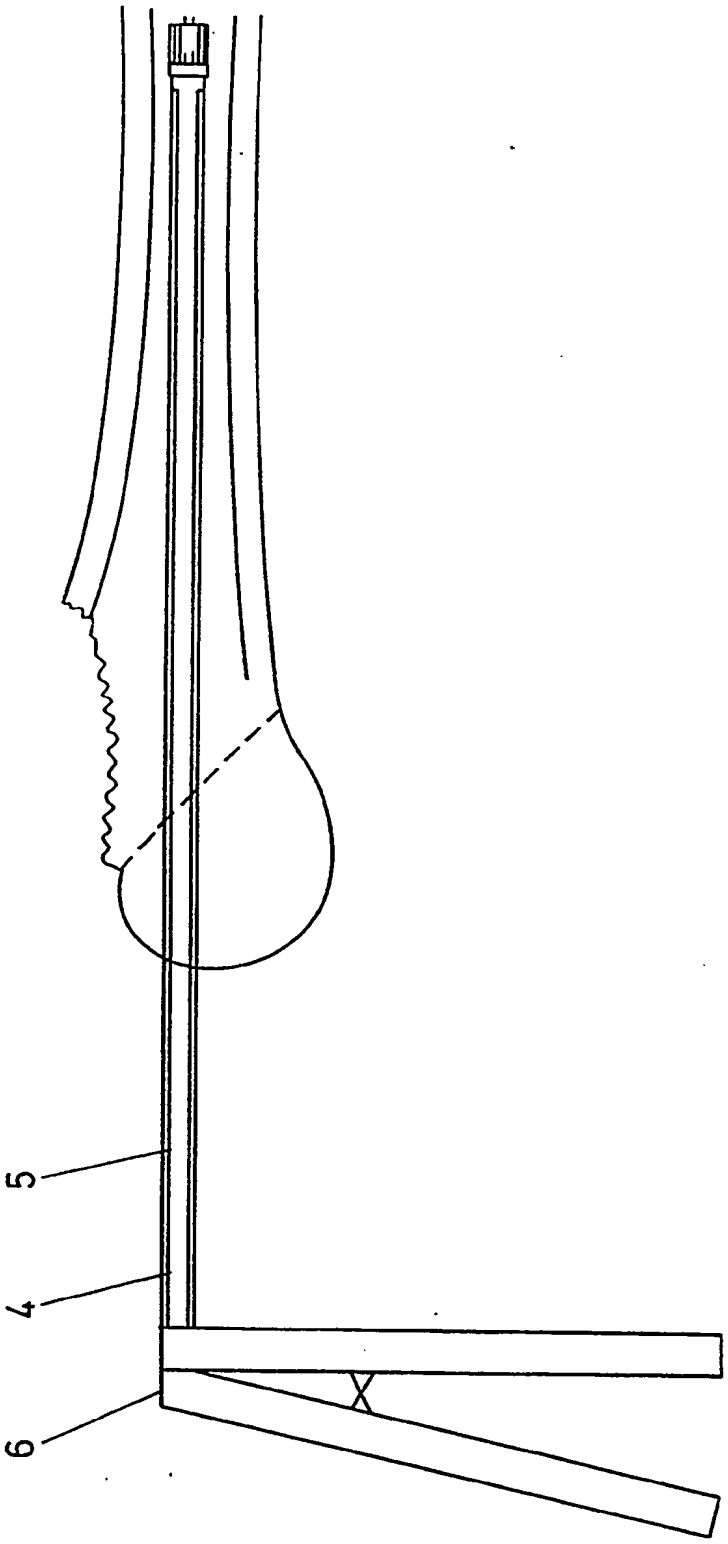

FIG. 4

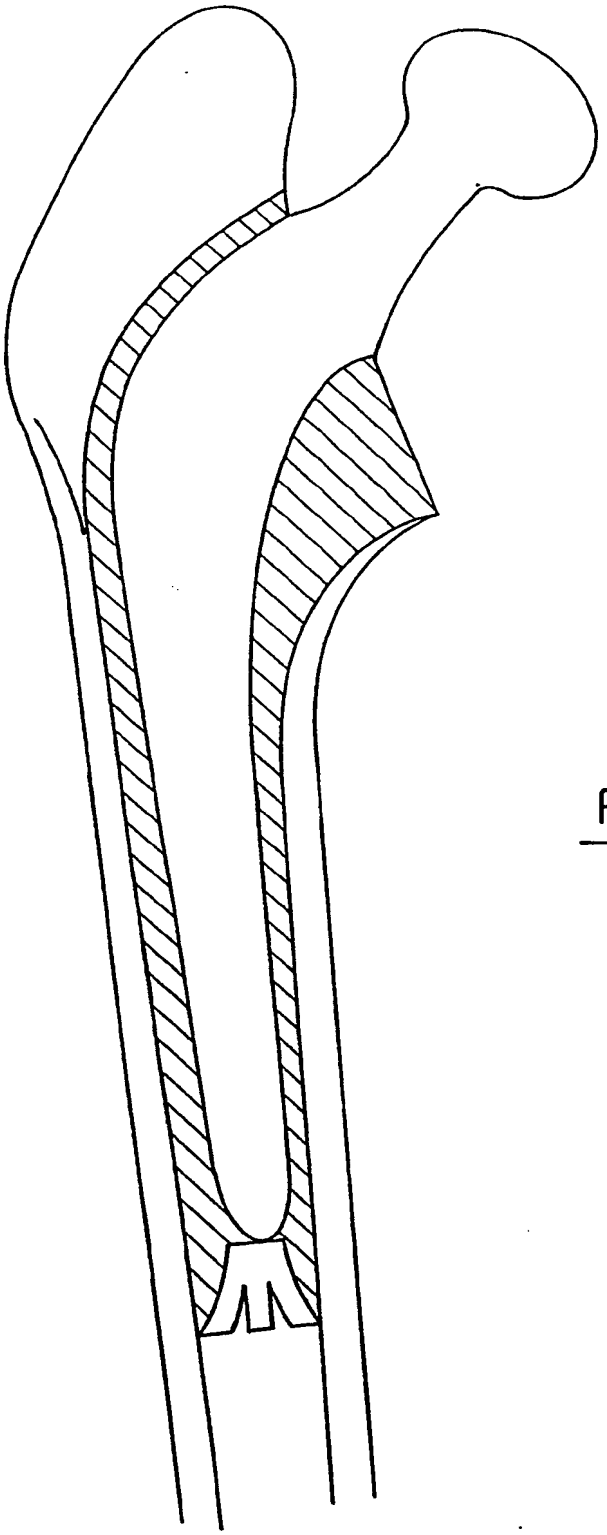

FIG. 5

CEMENT RESTRICTOR

This invention relates to a cement restrictor for preventing cement from extending beyond the distal tip of the femoral component of a hip prosthesis during a joint implant operation.

The use of a cement restrictor in the medullary canal of the femur has been widely advocated in total hip arthroplasty in which acrylic cement is used. A complication of this procedure is the aseptic loosening of components. It has been shown that this is partially caused by a failure at the bone cement interface. In addition this failure is compounded by incomplete filling of the femoral canal caused by cement being allowed to pass too far down the femur. Additional effects include the fracturing of the tip of the cement mantle distal to the end of the prosthesis. The use of a plug or cement restrictor will prevent the spread of the cement beyond a pre-determined point. This will allow the femoral canal to be filled completely. Insertion of the prosthesis into this closed space will cause a rise in pressure thus resulting in the inter-digitation of the cement with the bone. Placing of the cement restrictor at the position of the distal tip of the prosthesis will of course eliminate problems caused by the fracture of the distal tip of the cement.

A variety of techniques have already been employed for sealing off the medullary canal including a cylinder of bone taken from the resected femoral head during the operation, a cylinder of cement moulded during the operation and a number of artificial devices which act as cement restrictors. These are made from bio-compatible

material.

However, there are a number of problems with such devices. Bone used for the proposal of blocking the medullary canal may not be available especially at revision surgery. The cylinder of cement has to fit exactly the inside profile of the femur which is difficult with a limited number of moulds. Other artificial devices do not always fit securely in the medullary canal and may be pushed down the femur when the prosthesis is introduced. In addition the more secure devices tend to be complicated to implant.

A known cement restrictor is described in United States patent application no 4447915. The cement restrictor described therein comprises a deformable and expandable outer body having a jacket formed of a number of segments, and a conical expansion body which is pulled into the outer body, in order to expand the outer body. Spreading of the outer body causes anchoring elements to hook into the inner wall of the bone. The two bodies are permanently secured together by serrations on the inside of the outer body and the outside of the expansion body.

A disadvantage of this known cement restrictor is that when the expandable outer body is in the expanded state, the segments of the outer body are widely spaced apart from one another, and thus the restrictor does not form a good plug. Although the expansion body serves to a certain extent to close the spaces between the opened segments, spaces nevertheless remain and reduce the plugging ability of the restrictor.

In addition, the expansion body does not contribute to holding the restrictor in place, and thus the barbs formed in the outer body are necessary to allow the restrictor to be secured in place within the canal.

According to a first aspect of the invention there is provided a cement restrictor comprising:

an expandable body having a first end and a second end, and a closed state and an expanded state, the expandable body comprising an outer member formed from a plurality of longitudinal first portions extending from the first end towards the second end, and an inner member positioned co-axially within the outer member and comprising a plurality of longitudinal second portions extending from the first end towards the second end, and means for preventing rotational movement of the outer member relative to the inner member, wherein, when the expandable body is in the contracted state, the respective longitudinal portions of the inner and outer members are close to or in contact with one another, and when the expandable body is in the expanded state, the longitudinal first portioins are spaced apart from one another and substantially fill the spaces formed between adjacent first portions.

With the cement restrictor according to the invention therefore, the expandable body may be secured in a medullary canal by means of the inner and outer members digging into the bone of the canal. Once the expandable body is in position, it provides an effective blockage of the canal, due to the circumferential overlapping of the first and second longitudinal portions.

Preferably, the fixing means comprises a lug provided on the inner member and locatable in a recess on the outer member. The lug may thus be snap fitted into the recess to hold the members in position and to prevent rotational movement of one member relative to the other.

Advantageously, the cement restrictor further comprises an

expansion body positionable within the inner member such that the expandable body may be caused to expand by pulling the expansion body through the expandable body from the first end towards the second end.

By means of the expansion body, the expandable body may be simply expanded by pulling the expansion body relative to the expandable body.

Preferably the expansion body comprises a first end and a second end, and a cylindrical portion extending from the first end towards the second end, and conical portion extending from the second end to the cylindrical portion wherein the expansion body is positionable within the expandable body by inserting the first end of the expansion body into the inner member.

When the expansion body is inserted into the expandable body, the cylindrical portion of the expansion body is the first part of the expansion body to enter the expandable body. By shaping the expansion body in this way, entry of the expansion body into the expandable body is facilitated. The expansion body may be inserted at least partially into the expandable body without causing expansion of the expandable body. This may be useful in that the expansion body and the expandable body may be moved together into position in the medullary canal prior to expansion of the expandable body.

Conveniently, the lug of the inner member comprises a circumferential lug recess, and the expansion body comprises a first flange positioned at the first end of the expansion body and a second flange spaced apart from the first flange each of which flanges are locatable within the lug recess.

In use, the expansion body may be located in the expandable body by locating the first flange in the lug recess. In this position the expandable body is held in a closed state, and the cement restrictor may be moved within the canal until it is appropriately positioned. When the restrictor is at an appropriate position, the expansion body may be pulled through the expansion body until the second flange is located in the recess. The expansion body is then held in an expanded state.

The cement restrictor according to the first aspect of the invention is expandable in situ to a size appropriate to the canal in which it is positioned. It is therefore not necessary to accurately size the restrictor.

According to a second aspect of the invention, there is provided a set of three cement restrictors according to the first aspect of the invention, which restrictors are of a different size to the others, wherein a medullary canal of any size may be plugged with one of the restrictors of the set.

Previously, with known cement restrictors, it has been necessary to accurately size a restrictor to suite a particular canal size.

Advantageously, the end of the outer member at the second end of the expandable body is shaped to receive the femoral prosthesis once the restrictor is in position. This allows the prosthesis to be centralised in the medullary canal, and to be accurately positioned.

Preferably the cement restrictor further comprises an introducer comprising an inner rod which is engageable with the first end of the expansion body, and an outer graduated tube which indicates how far down the canal to place the

cement restrictor.

The invention will now be described by way of example only with reference to the accompanying drawings in which:

Figure 1 is a schematic diagram of the inner member, the outer member, and the expansion member;

Figures 2a, and 2b are schematic diagrams of the cement restrictor according to the invention in a closed and an expanded state respectively;

Figure 3 is a schematic diagram of an introducer according to the invention;

Figure 4 is a schematic diagram showing the cement restrictor and the introducer in situ in a medullary canal; and

Figure 5 is a schematic diagram of the cement restrictor according to the invention in place with a femur prosthesis positioned at one end of the outer member.

Referring to Figure 1, components of a cement restrictor according to the present invention are shown. The cement restrictor comprises an outer member 1 and an inner member 2 which is positionable within the outer member 1. In a non-expanded state, each of the members 1, 2 has a substantially circular cross section. The members 1, 2 are each formed from a plurality of longitudinal segments 3, 4, which in a non-expanded state are positioned very close to if not touching one another. The restrictor further comprises an expansion body 5 which is positionable within the inner member 2. The expansion body 5 comprises a first end 6 and a second end 7 and is formed from a cylindrical portion 8 which extends from the first end, and a conical portion 9 which extends from the second end to meet the cylindrical portion 8. The expansion body 5 further comprises a first flange 10 and a second flange 11 which extends circumferentially around the cylindrical portion. The first flange 10 is positioned at the first end 6 and

the second flange 11 is spaced apart from the first flange 10.

Referring to Figures 2a, the cement restrictor 10 is described in more detail. As can be most clearly seen from Figures 2a and 2b, the inner member 3 comprises a lug 20 which is fittable into a recess 21 in the outer member 1. The members 1, 2 may thus be fixed in position by snap fitting the lug 20 into the recess 21. When fitted together in this way, rotational movement of one member relative to the other is prevented. This ensures the correct positioning of the segments 3, 4 relative to one another. The expansion body 5 is insertable into the inner member 2 by positioning the first end 6 into the inner member 2. When the expandable body is in a completely unexpanded state, the expansion body may be held in place by means of a collar 22 which is locatable within a recess 23 in the lug 20. In use, the expansion body 5 may be pulled through the expandable body in the direction of the arrows in each of Figures 2a to 2c and may be held relative to the expandable body by means of first flange 10 which locates in the recess 22. In this position, the expandable body is in a closed state, and may, together with the expansion body be easily moved within a medullary canal in order to locate the restrictor at an appropriate position. Referring to Figure 2b, once the restrictor has been located in an appropriate position further pulling the expansion body 5 through the expandable body results in the expansion body 5 being located relative to the expandable body by means of a second flange 11 which locates on the recess 22. In this position, the expansion body is held in a fully expanded state. In this position, the expandable body will dig into the bone of the canal and hold the restrictor in position.

Referring to Figure 3 an introducer 30 is shown, which may

be used to pull the expansion body 5 through the expandable body, and also to move a restrictor to an appropriate position within the canal. The introducer comprises an inner rod 31 and an outer tube 32 which are operated by a handle 33. In use, the rod 31 is attached to the cylindrical portion 8 of the expansion body 5 by means of holes in the cylindrical portion 8. The cement restrictor is first positioned at an appropriate point of the canal, by means of markings on the outer tube 32 which allow a surgeon to determine how far down the canal to place the cement restrictor for the prosthesis being used on any given occasion. The expansion body 5 is then pulled through the expandable body by the action of squeezing the handles 33, until the second taper 11 is located in the recess 22. This causes the restrictor to fully expand and remain expanded. Once expanded, the introducer continues its motion to retract causing the threads of the core to shear as the introducer is removed.

Typically, the restrictor is made from a bio-compatible polymer. This polymer could be either polyethylene or alternatively a bio degradable polymer.

The inner and outer members 1, 2 which are each formed from longitudinal portions which form leaves, are also formed on their inside surfaces with ridge features. In addition, the cylindrical portion of the expansion body is also formed with ridges on its outer surface. The ridges on the inner and outer members can thus interlock with the ridges on the expansion body. In use, as the expansion body is pulled through the expandable body, the ridges on the expansion body and the ridges on the expandable body act as ratchets thereby locking the expansion body in position. The conical portion of the expansion body presses against the second end of the expandable body forcing the leaves to expand. The leaves will continue to expand until they are

forced against the inside of the medullary canal, thereby locking the device in position and sealing off the canal. Due to the fact that the expandable body is formed from two members, the inner and outer member, which are positioned relative to each other such that the respective leaves overlap circumferentially, an effective blockage of the canal is provided.

Referring to Figure 4, the restrictor according to the invention is shown in situ in a medullary canal. Pre-operatively, the patient is assessed radiographically to determine which size of restrictor to use. Before insertion, the patient is anaesthetized and is prepared for a total hip anthroplasty. The head and neck of the femur are resected in the usual manner. The femural canal is then prepared in the conventional way with a combination of rasps, reamers and gouges. Care should be taken to remove any relatively soft and loose tissue. The graduations on the introducer will allow the surgeon to insert the device to the desired depth. At this point the introducer is squeezed gently by means of the handles 33. This has the effect of expanding the device by pulling the expansion body through the expandable body. This should be maintained until the device is locked in place. The introducer will allow a medullary canal of any long bone (femur, tibia, and humerus) to be blocked off in a similar manner. At the same time, the introducer is disconnected from the implanted device. The prosthesis is then inserted in the usual way until the tip of the prosthesis rests on the proximal portion of the outer member thereby centralising the prosthesis, as shown in Figure 5.

Because of the variable diameter of the cement restrictor according to the present invention, a set of restrictors which are suitable for use in any medullary canal may be formed with only three sizes of restrictor. The present

invention provides a restrictor which will resist further movement after deployment down the medullary canal, and which is easily removed when required. Further it allows correct positioning of the distal tip of the prosthesis used in the implant. The restrictor is made radio opaque by the inclusion of an x-ray marker ball.

CLAIMS

1. A cement restrictor comprising:

an expandable body having a first end and a second end, and a closed state and an expanded state, the expandable body comprising an outer member formed from a plurality of longitudinal first portions, extending from the first end towards the second end, and an inner member positioned co-axially within the outer member and comprising a plurality of longitudinal second portions extending from the first end towards the second end, and means for preventing rotational movement of the outer member relative to the inner member, wherein when the expandable body is in the contracted state, the respective longitudinal portions of the inner and outer members are close to or in contact with one another, and when the expandable body is in the expanded state, the longitudinal first portions are spaced apart from one another and substantially fill the spaces formed between the adjacent first portions.

2. A cement restrictor as claimed in claim 1 wherein the fixing means comprises a lug provided on the inner member, and locatable in a recess on the outer member.

3. A cement restrictor according to claim 1 or claim 2 further comprising an expansion body positionable within the inner member, such that the expandable body may be caused to expand by pulling the expansion body through the expandable body, from the first end towards the second end.

4. A cement restrictor according to any one of the preceding claims wherein the expansion body comprises a first end and a second end, a cylindrical portion extending from the first end towards the second end, and a conical portion extending from the second end to the cylindrical portion wherein the expansion body is positionable within the expandable body by inserting the first end of the expansion body into the inner member.

5. A cement restrictor according to any one of claims 2 to 4 wherein the lug of the inner member comprises a circumferential lug recess, and the expansion body comprises a first flange positioned at the first end of the expansion body and a second flange spaced apart from the first flange, each of which flanges are locatable within the lug recess.

6. A cement restrictor according to any one of the preceding claims wherein the end of the outer member at the second end of the expandable body, is shaped to receive a femoral prosthesis once the restrictor is in position.

7. A cement restrictor according to any one of the preceding claims further comprising an introducer comprising an inner rod, which is engageable with the first end of the expansion body, and an outer graduated tube which indicates how far down a medullary canal to place the cement restrictor.

8. A set of three cement restrictors according to any one of the preceding claims, each of which restrictors is of a different size to the others, wherein a medullary canal of any size may be plugged with one of the restrictors of the set.

Patents Act 1977
Examiner's report to the Comptroller under Section 17 (The Search Report)

Application number
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Relevant Technical fields

(i) UK Cl (Edition K) A5R (RAM)

(ii) Int Cl (Edition 5) A61F

Search Examiner
R J WALKER

Databases (see over)

(i) UK Patent Office

(ii)

Date of Search
9 APRIL 1992

Documents considered relevant following a search in respect of claims 1 TO 8

Category (see over)	Identity of document and relevant passages	Relevant to claim(s)
Y	US 4447915 (WEBER) acknowledged in application, see whole document	1, 3, 6, 7, 8
A	US 4276659 (HARDINGE) see Figure 3 and column 2 lines 7-13	1
Y	US 4245359 (STUHMER) note column 2 lines 36-38	1, 3, 6, 7, 8

Category	Identity of document and relevant passages	Relevant to claim(s)

Categories of documents

X: Document indicating lack of novelty or of inventive step.

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P: Document published on or after the declared priority date but before the filing date of the present application.

E: Patent document published on or after, but with priority date earlier than, the filing date of the present application.

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